## REMARKS

Applicant thanks Examiner Hobbs for her detailed review of the pending claims. Applicant has amended claims 1, 3-12, 14, 15 and 16. New claims 19 and 20 have been added. Claims 17 and 18 have been canceled. No new matter has been added.

Objections to Claims 14-16

Claims 14-16 were objected to because multiple dependent claims 14 and 16 were in multiple dependent form and depended from claim 12, which was also in multiple dependent form. Clams 12, 14, and 16 have been amended to avoid multiple dependencies. Thus, the objection is believed to be moot.

Rejection of Claims 17 and 18 Under 35 U.S.C. § 112, ¶ 2

Claims 17 and 18 were rejected as indefinite under 35 U.S.C. § 112, ¶ 2. Claims 17 and 18 have been canceled, and the rejection is moot.

Rejection of Claims 1-11 Under 35 U.S.C. § 103(a) Based on Orenga, Rambach, Sakai, and Tani

The Examiner has rejected claims 1-11 as obvious under 35 U.S.C. § 103(a) based on the combination of Orenga, U.S. Patent No. 5,534,415, Rambach, U.S. Patent No. 5,716,799, Sakai, *Biochem Biophys Acta* 1308:81-87 (1996), and Tani, *Appl. Microbiol. Biotechnol.* 34:5-9 (1990). The rejection is respectfully traversed.

Claim 1 recites a medium for detecting and/or identifying a *Candida* yeast which comprises a chromogen, carbohydrate in the range of 1-5 grams/liter, and an alcohol. The growth of the *Candida* yeast in the medium under appropriate conditions results in hydrolysis of the chromogen to generate a chromophore of a derived color. The derived color is different from the color generated by hydrolysis of the chromogen in a standard medium that includes the same chromogen and carbohydrate in the same concentrations but without the alcohol. Orenga's medium does not give

rise to a derived color. Claim 1 reflects the unexpected result that a medium for detecting and identifying a *Candida* yeast can be prepared by reducing the levels of carbohydrate in the *Candida* yeast medium and adding an alcohol component. The Rambach reference expressly requires a "high" carbohydrate concentration, which is outside of the claimed range:

> Hence the present invention relates to a method for demonstrating the presence or absence of a particular strain of microorganism in a medium, characterized in that at least one chromogen which is a substrate for an enzyme of the strain and at least one compound chosen from **a carbohydrate at high concentration** are introduced into the culture medium, so as to obtain after hydrolysis of the chromogen a color different from the basic color of the chromophore.
> * * *
> The **high carbohydrate concentration is of the order of 10 to 30 g/l of medium**.

Rambach at 2:14-21 and 26-27.

Rambach further makes clear that high levels of the carbohydrate component are critical to the production of derived color and contrasts the function of the carbohydrate when it is present at high levels to its function as a simple "carbon source" when it is present at low levels:

> Derived color is understood to mean any color whose dominant wavelength differs from the dominant wavelength of the chromophores liberated by the chromogens present in the culture medium, taken separately in a standard medium.
>
> Standard medium is understood to mean any ordinary identification medium in which the **carbohydrate has a simple function of carbon source**, at very low or even zero concentrations, where it is considered that such concentrations make it possible to avoid any inducing effect which would modify the behavior of the microorganisms in an uncontrolled manner and would induce errors in the identification of the microorganisms in question.

Rambach at 1:66-2:9 (emphasis added).

In its description of exemplary media that produce derived colors, Rambach again states that the addition of glucose (a carbohydrate under Rambach's definition of the term) is critical to the production of derived colors:

> The above results show that **the addition of glucose** and phosphate **makes it possible to broaden the range of colors available for the same medium**, making it possible here to distinguish seven different species, and especially to identify *Candia albicans* unambiguously.

Rambach at 4:1-5 (emphasis added).

Orenga teaches the use of a carbohydrate merely as a carbon source. Orenga at 3:51-55. The Examiner suggests that one of ordinary skill would have selected Orenga's levels of a carbon source (0-10 g/l) and somehow combined the Orenga medium with the Rambach medium to obtain the claimed invention. However, Rambach specifically teaches away from this possibility by teaching that the carbohydrate component of the medium must be present in levels that are high enough to allow it to function other than as a simple carbon source and that those levels are 10-30 g/l of the medium. "[W]hen the prior art teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." *KSR International v. Teleflex, Inc.*, 127 S. Ct. 1727, 1740 82 U.S.P.Q.2d 1385 (2007). Put differently, if Rambach were combined with Orenga, Rambach would not work for its intended purpose. See *In re John R Fritch*, 972 F.2d 1260, 1265 n.12 (Fed. Cir. 1992) ("This court has previously found a proposed modification inappropriate for an obviousness inquiry when the modification rendered the prior art reference inoperable for its intended purpose")

As indicated in Applicant's specification, alcohols would be expected to inhibit the growth of *Candida* yeasts at certain concentrations. Applicant's Published Application at 6 and 10 (note 4). Thus, the claimed invention achieves the unexpected result of reducing carbohydrate levels while still achieving selectivity and the claimed derived color while avoiding the undesirable alcohol-induced inhibition of *Candida* yeasts. The reduction of carbohydrate levels beneficially reduces the likelihood of disruptive bacterial growth which could negatively impact the ability of the medium to detect the *Candida* yeast. As indicated in Applicant's specification, a commercial embodiment of the Rambach patent is supplied under the name CHROMagar Candida. Published Application at 2. As indicated in Table 2 of Applicant's specification, the medium of claim 1 provides results that are

at least as good as CHROMagar Candida notwithstanding the use of lower levels of carbohydrate which are outside of Rambach's 10-30 gms/litre range.

The other unexpected result achieved by the claimed invention is that it selectively detects *Candida* yeasts quickly without a hexosamine activator, the use of which is taught by Orenga. As indicated in Applicant's specification, a commercial embodiment of the Orenga medium is supplied under the name "Candida ID." As discussed at page 14 of Applicant's published specification, the medium of claim 1 detects of *Candida* yeasts as quickly as the Candida ID medium without using a hexosaminide activator. Example 2, pp. 13-14 of Published Application. New claim 20 expressly recites the lack of a hexosamine activator and further distinguishes the cited references.

The Examiner relies on Sakai for its teaching that methanol can be used as a carbon source for producing glucoamylase from *Candida boidinii* and on Tani for its teaching that methanol can be used to produce citric acid from *Candida sp. Y-1*. This is important, because not all carbon sources are capable of generating derived colors. For example, Applicant's specification teaches that other carbon sources, such as succinate, citrate, and ethyl actetate are ineffective at producing derived colors, so there would be no reason to expect that the high concentration of carbohydrate taught by Rambach could be replaced with any "carbon source," as the Examiner suggests. One of ordinary skill would not have had a reasonable expectation of success in using methanol as a carbon source to reduce the levels of carbohydrate required by Rambach for a selective medium. Moreover, neither reference suggests the unexpected results obtained by the medium of claim 1, i.e., a medium that produces derived colors for selective detection of *Candida* yeasts comparable to that provided by Rambach in a time frame comparable to that of Orenga without using the high levels of carbohydrate called for by Rambach and without using the hexosamine activator called for by Orenga. Thus, reconsideration and withdrawal of the rejection are respectfully requested.

Applicant's dependent claims further distinguish the cited references. For example, claim 3 recites that the carbohydrate is present in an amount in the range from 2-4 gms/litre. As mentioned above, Rambach requires 10-30 gms/litre of medium. The only "carbohydrate" mentioned by Orenga is glucose. Orenga at 3:54-55. Orenga specifies a preferred glucose level of 1 gm/litre,

which is expressly outside of the range of claim 3. Neither Sakai nor Tani compensates for Orenga and Rambach's deficiencies.

Claim 9 depends from claim 1 and recites that the alcohol component of the claimed medium comprises ethanol. Claim 19 depends from claim 1 and recites that the alcohol includes at least about 85 percent by weight ethanol. Sakai does not disclose or suggest the use of an alcohol comprising any amount of ethanol. Tani does not disclose or suggest the use of an alcohol comprising at least 85% ethanol. Moreover, Tani teaches away from the use of ethanol as a carbon source by discouraging the use of methanol as a carbon source for producing citric acid from a fluoroacetate resistant mutant strain, MA 92, of *Candida* sp. Y-1. Tani at 9. Tani further discourages the use of ethanol by stating that unlike ethanol, methanol can produce energy via multiple pathways:

> Ethanol goes directly into the TCA [tricarboxylic acid] cycle after oxidation into acetaldehyde and acetyl-CoA, so energy generation from ethanol would mainly depend on the TCA cycle. On the other hand, energy can be generated through other pathways (e.g., glycolysis or methanol oxidation) in addition to the TCA cycle when cells are grown on glucose or methanol. When cells of MA92 were grown on ethanol, low aconitase activity might have caused alack of energy for effective citric acid production because of excessive dependence on the TCA cycle.

Tani at 9.

## CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Any fees due with this response are identified in the accompanying fee transmittal. If any additional fees are due, please charge our Deposit Account No. 18-0013, under Order No. 66311-0360 from which the undersigned is authorized to draw.

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